UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

EASTERN MAINE MEDICAL CENTER,	)	
Plaintiff,	)	
v.	)	Civil No. 05-7-B-H
HEALTH AND HUMAN SERVICES, SECRETARY,	)	
Defendant.	)	

RECOMMENDED DECISION ON CROSS-MOTIONS FOR JUDGMENT ON THE ADMINISTRATIVE RECORD

Plaintiff Eastern Maine Medical Center (EMMC) cares for patients having End Stage Renal Disease (ESRD) by providing them with, primarily, dialysis treatments that are reimbursed through the Medicare program administered by the Department of Health and Human Services. In August 2000, EMMC submitted a "Composite Rate Payment Exception Request" in which it sought to be compensated for dialysis treatments at a rate substantially above the "composite" national (or default) rate that Medicare pays health care providers for each dialysis treatment they provide. The Department denied the request over successive administrative appeals, asserting that the request was not supported by adequate documentation. EMMC contends in this action that the administrative denial of its request was arbitrary and capricious. EMMC also claims that the Provider Reimbursement Review Board (PRRB), which conducted a hearing on the request, violated EMMC's due process rights by denying EMMC's request that the PRRB issue subpoenas requiring that the individuals who performed the first and second stage administrative review of the request appear at the hearing to give testimony and produce their

files. The matter is currently before the Court in the context of cross-motions for judgment on the administrative record. I conclude that the existing record does not reflect an administrative determination that was arbitrary and capricious and that the "due process" theory advanced by EMMC does not require a remand.

BACKGROUND

"Pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395-1395ccc, Medicare reimbursement is available for Medicare beneficiaries who have been diagnosed with End Stage Renal Disease ('ESRD')." Children's Hosp. v. Shalala, 2 Fed. Appx. 141, 142, 2001 U.S. App. LEXIS 979 at *2 (2d Cir. 2001) (unpublished opinion). "Facilities providing ESRD medical services and treatment ('providers') are reimbursed through the medicare Part A program in accordance with 42 U.S.C. 1395rr and 45 C.F.R. Part 405, Subpart U." Id.

> Each year, the Secretary of Health and Human Services establishes a prospective "composite rate" for various outpatient treatments of end-stage renal disease (ESRD). The composite rate, which represents the approximate per-treatment cost that the Secretary expects health-care providers to incur for various ESRD treatments, encourages efficiency, for if a provider's per-treatment cost falls below the composite rate, then the difference represents a profit to the provider. At the same time, the composite rate does not establish an absolute ceiling; providers that experience per-treatment costs above the composite rate may ask the Secretary for an "exception." 42 U.S.C. § 1395rr(b)(7).

St. Luke's Hosp. v. Thompson, 355 F.3d 690, 691-92 (D.C. Cir. 2004) (citing 48 Fed. Reg. 21,254 (May 11, 1983) and 42 U.S.C. § 1395rr(b) (2000) in regard to the Secretary's annual duty to establish the composite rate). See also Aroostook Med. Ctr. v. Leavitt, 365 F. Supp. 2d 51, 52 (D. Me. 2005) (describing the "prospective" nature of Medicare's ESRD payments). Exceptions may be awarded for elevated per-treatment costs based on the following criteria:

(a) Atypical service intensity (patient mix)[;]

(b) Isolated essential facility[;]

(c) Extraordinary circumstances[;]

(d) Self-dialysis training costs[;]

(e) Frequency of dialysis[.]

42 C.F.R. § 413.182. In order to obtain an exception to the composite rate, the provider must demonstrate "by convincing objective evidence, that its total per treatment costs are reasonable and allowable . . . and that its per treatment costs in excess of its payment rate are directly attributable to" a given criterion. Id.

> Pursuant to HHS's Provider Reimbursement Manual (PRM) . . . providers must submit exception requests during 180-day periods that the Secretary designates from time to time . . . . Providers submit requests to their "fiscal intermediaries," i.e., private organizations such as insurance companies. Intermediaries have fifteen working days to review requests and forward them to HHS with their recommendations. The HHS division responsible for initially reviewing exception requests, the Centers for Medicare & Medicaid Services (CMS), has sixty working days in which to deny requests, or they are automatically approved. 42 U.S.C. § 1395rr(b)(7). Because this sixty-day period includes the fifteen days that intermediaries have to review applications, CMS actually has only forty-five working days in which to complete its review.

Id. (citations to PRM omitted).

The PRRB's decision is reviewed pursuant to the Administrative Procedures Act, 5 U.S.C. § 706. See 42 U.S.C. § 1395oo(f)(1). Thus, the Court should affirm the administrative determination unless it is demonstrated to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." St. Luke's Hosp., 355 F.3d at 694 (citing 42 U.S.C. § 1395oo(f)(1); 5 U.S.C. § 706(2)(A) (2000)). "An agency's interpretation of its own regulations is generally given controlling weight provided it is not plainly erroneous or inconsistent with relevant statutes." Children's Hosp. of Buffalo v. Apfel, 110 F. Supp. 158, 164 (W.D.N.Y. 1999) (citing Chevron U.S.A. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984)). "Such 'broad deference' is especially warranted in actions where the subject regulations concern a

'highly technical' and 'complex' regulatory program." Id. (citing Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (considering Medicare reimbursement regulations as "highly technical" and "complex")). Finally, the court is to consider only the bases upon which the agency actually relied in reaching its decision. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971).

EMMC provides ESRD medical services and treatment through its Bangor, Maine, and Ellsworth, Maine, hospital facilities. This case concerns EMMC's request for an increase in the amount it receives from Medicare in compensation for dialysis services. In December 1999, the Centers for Medicare & Medicaid Services (CMS)[1] issued new composite rates for dialysis treatments furnished on and after January 1, 2000. The rate announced for hospital-based dialysis in EMMC's region was $124.32 per treatment. CMS announced that it would open a 180-day "window" to file requests for exceptions from the composite rate, which window would be open between March 1 and August 28 of 2000. EMMC filed an exception request on Thursday, August 24, 2000. The 180-day window closed the following Monday. In its request, EMMC sought an increase in its rate for dialysis treatments based on three criteria: atypical service intensity (ASI), isolated essential facility (IEF) and based on its provision of accelerated training (AT) to patients having home dialysis machines. EMMC sought an additional $74.52 in per treatment compensation consisting of $30.06 based on the ASI criterion, $43.34 for the IEF criterion, and $1.12 for the AT criterion. In accordance with Medicare regulations, EMMC's request was first reviewed by its Medicare fiscal intermediary, Associated Hospital Services of Maine (the "Intermediary"), which reviewed the request and forwarded it to CMS on September 8, 2000, with a recommendation. In its cover letter to CMS, the Intermediary opined that the

[1] The documents in the record reflect that CMS was formerly known as the Health Care Financing Administration, or HCFA. "On July 1, 2001, the Health Care Financing Administration changed its name to the Centers for Medicare and Medicaid Services." Aroostook Med. Ctr., 365 F. Supp. 2d at 52 n.4.

documentation accompanying the request was adequate in most respects, but recommended that any rate increase be limited to $54.59, finding that the AT request was not adequately supported and that there were certain unexplained variances concerning FY 1999 costs and the costs EMMC projected for FY 2001. CMS declined to follow the recommendation. In a letter dated November 9, 2000, CMS denied the request altogether, for reasons stated below. EMMC appealed that decision and a hearing was held before the Provider Reimbursement Review Board (PRRB) on December 12, 2004. Prior to the hearing, EMMC requested that the PRRB issue a subpoena requiring the attendance at the hearing of the Intermediary representative who had reviewed EMMC's request and recommended an increase and another subpoena requiring the attendance of the CMS representative who rejected the Intermediary's recommendation. The subpoena request also sought certain documents that might be in the possession of the Intermediary or CMS. The PRRB denied the subpoena requests. Following the hearing, on November 18, 2004, the PRRB affirmed CMS's decision. The parties agree that EMMC's right to pursue the pending petition for judicial review was preserved by this administrative process. See 42 U.S.C. § 1395oo(f).

DISCUSSION

I address the issues related to the denial of EMMC's exception request before turning to EMMC's due process allegations.

A. EMMC's Composite Rate Exception Request

1. Isolated and essential facility

The PRRB concluded that EMMC's exception request was appropriately denied based on a lack of documentation. According to the PRRB, the inadequacies in EMMC's documentation include, but are not limited to, shortcomings in the data EMMC submitted with respect to the

travel burdens that would be imposed on EMMC's dialysis patients if they could not obtain ESRD services at EMMC and had to travel to the next nearest facility. Among the requirements listed to qualify for an IEF exception are the following:

> (1) The facility must be the only supplier of dialysis in its geographical area;
>
> (2) The facility's patients must be unable to obtain dialysis services elsewhere without substantial additional hardship; and
>
> (3) The facility's excess costs must be justifiable.

42 C.F.R. § 413.186(a). The regulation requires the provider to document, among other things:

> (i) That a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship; and
> (ii) The additional hardship the patients will incur in travel time and cost.

Id. § 413.186(c)(2). In addition, the provider must supply:

> (vii) A list of patients by modality showing commuting distance and time to the current and the next nearest renal dialysis facility.

Id. § 413.186(c)(4)(vii).

EMMC's request reflects that it is approximately 41 miles away from an ESRD facility in Belfast, 56 miles from another facility in Waterville and 76 miles from a third facility in Augusta. (AR at 9.) The Secretary contends that the IEF exception was appropriately denied by the PRRB because EMMC failed to support its request with real data reflecting the travel burdens that EMMC's patients would experience if they had to travel to the next nearest ESRD facility rather than to EMMC. (Def.'s Mot. at 9, Docket No. 16.) In its decision affirming CMS's denial, the PRRB observed that "the Provider submitted the distance that its patients drive to the Provider's facility but did not furnish the distance to the nearest alternate dialysis facility as the regulations require." (Admin. Record (AR) at 9.) With respect to the issue of the distance patients would have to travel to the next nearest facility, EMMC asserts that "using the residence

information, maps, and mileage information contained in the Request (AR 887-890, 892-907, 910-914, 920-924, 927-933), it is clear that a substantial number of the Provider's permanent patients would face additional hardship if the Provider ceased its operations." (Pl.'s Mot. at 8, Docket No. 14.) In effect, EMMC does to this Court exactly what it did to CMS: it invites the Court to fill in the gaps in its submission. According to EMMC, all of its patients who live North and East of Bangor would have to travel through Bangor to get to the next nearest facility and, therefore, the travel time from EMMC to the next nearest facility is the most appropriate figure. Moreover, argues EMMC, because there is no evidence in the record that the two closest facilities could possibly expand to absorb all of EMMC's dialysis patients if EMMC stopped providing those medical services, the Court should consider the 75 miles to Augusta as the distance that most of its patients would have to travel. (Id. at 9.)

The relevant data on distances and travel time that EMMC submitted in support of its request can be found at pages 910-914 of the Administrative Record. In addition, on page 682 the Court can find EMMC's summary of the additional burden in lost time and dollars that EMMC says its patients would incur if EMMC ceased operating its ESRD facilities. A review of the worksheet prepared by EMMC reflects that the provider essentially did not bother to offer the distances and times that its patients would have to travel to obtain services at alternative ESRD facilities. Instead, for most entries under the column "mileage to nearest facility," EMMC entered the distance to its own facility. According to the consultant who oversaw the preparation of the request, these errors arose because the individual who filled in the worksheet failed to understand that the "nearest facility" column was supposed to collect data regarding travel distance and time to the "next nearest facility." (AR at 134.) For many other entries, however, EMMC simply left the space blank. Based on my review, the blank entries appear to be

associated with patients who live in locations that are as near to another facility as they are to EMMC's facility, but that possibility is apparent to me only because of my familiarity with the towns and cities of Maine. I do not presume that a member of the PRRB in Baltimore would share this familiarity. The other, admittedly erroneous, entries appear to be for patients living in the vicinity of Bangor or to the north and east of Bangor. EMMC asserts in its motion for judgment that anyone reviewing its request should have understood from the narrative statements at page 682 of the record that these patients would have to travel through Bangor in order to reach another facility and, therefore, their additional travel burden could have been determined by simply using the travel distance from EMMC to the other facilities. (Pl.'s Mot. at 8.)[2] I note, for what it is worth, that this representation is not accurate. Among those patients living north of Bangor are some who would not likely travel to Bangor in order to access, for example, a Waterville or Augusta ESRD facility. I have in mind here patients located in Piscataquis County and Western Penobscot County who would likely travel south on Route 7 rather than Route 15, thereby avoiding Bangor altogether and shaving many miles from a trip south. In any event, however apparent it is to a resident of Bangor that the region is relatively "isolated," the question here is not simply, as EMMC suggests, whether its request was substantially good enough for a government bureaucrat to puzzle it out, but whether the Secretary and the other administrative arms of the Department of Health and Human Services abuse their discretion when they deny a request for a substantial (greater than 30 per cent) exception to the composite rate to a provider who cuts corners in its request by offering only broad brush estimates rather than specific data. I conclude that the standard of review favors the government on this question, particularly when

[2] In EMMC's words, "using the residence information, maps, and mileage information contained in the Request (AR 887-890, 892-907, 910-914, 920-924, 927-933), it is clear that a substantial number of the Provider's permanent patients would face additional hardship if the Provider ceased its operations." (Pl.'s Mot. at 8.) It is difficult to understand why EMMC did not perform this task itself.

this shortcoming in the request is coupled with the other concerns over documentation raised by CMS and the PRRB (and even the Intermediary), as discussed below. Cf. St. Lukes, 355 F.3d at 694-95 ("St. Luke's has not explained how requiring CMS to discern and then correct providers' errors is consistent with this burden of proof, or how evidence that is wrong could possibly be 'convincing.' Nor do we understand how we would distinguish between errors that are obvious and those that are not.").[3]

2. Atypical service intensity

As suggested above, the documentation problems were not limited to the IEF exception. The PRRB also found the following:

> With regard to the "atypicality" of its patients, the Provider's documentation and numbers were inconsistent. Specifically, the exact number of patients could not be validated, nor could the length of stay be determined. Thus the cost information necessary to support a rate increase could not be determined.

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[3] In Aroostook Medical Center v. Leavitt, Judge Carter took a dim view of a similar denial of an IEF exception request, observing:

> "[T]he Court notes that the Board's conclusion that AMC failed to submit adequate documentation concerning patient commuting distances borders on arbitrary and capricious. Elementary arithmetic would allow for computation of any alleged deficiencies in AMC's evidence. The record indicates that the distance from AMC to the next nearest facility in Bangor is 160 miles. AMC provided the distance each patient must travel to the AMC facility, but not to the Bangor facility. Simply subtracting the number of miles a patient had to travel to AMC from 160 would present the minimum number of miles a patient had to travel to the Bangor facility. Denial of AMC's exception request on this minor technicality is, as AMC suggests, a matter of form over substance.

365 F. Supp. 2d at 57 n.14. Unlike Aroostook Medical Center, located in Presque Isle, EMMC is within 76 miles of three other ESRD facilities and Exhibits 15 and 17 reflect that some of its patients are actually closer to these other facilities than they are to EMMC. I can understand why, in this case, an agency might well expect the provider to perform the "elementary arithmetic" in support of its request. When there are patients living in Searsport, Camden, Rockland, and West Rockport the mileage differential between traveling to EMMC in Bangor and the Waldo County Hospital in Belfast might well be represented as a negative number if one were to apply Judge Carter's suggestion. Belfast is, according to the record evidence, 41 miles from Bangor and a patient traveling from Camden would in all probability drive right through Belfast on their 56 mile, one hour and twenty-six minute commute to Bangor. On EMMC's submission (AR at 912) the mileage to the nearest facility and the travel time to the nearest facility columns are left blank for the Camden patient, as it is throughout the chart for other patients who might be in similar circumstances. This "missing" information forms part of the basis of the denial and it is hard for me in these circumstances to dismiss it as a "minor technicality."

(AR at 9.) EMMC argues that the PRRB's findings are not supported by the record. (Pl.'s Mot. at 10.) According to EMMC, the PRRB and CMS erroneously "misinterpreted" EMMC's documentation. (Id.) EMMC directs the Court to pages 687 and 928-933 of the record and asserts that these pages contained "all of the information necessary to verify" that there were 134 "permanent" patients as represented by EMMC. (Id.)[4] Again, I believe that the circumstances favor the Secretary.

In order to obtain an exception to the composite rate based on atypical service intensity (ASI), EMMC needed to "demonstrate that a substantial proportion of its outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients." 42 C.F.R. § 413.184(a)(1). According to the Secretary, EMMC's request failed to accurately indicate the *total* number of patients it had who received outpatient dialysis treatments, thereby calling into question what figure should be used as a denominator for calculating the proportion of its patients who required atypically intense services. (Def.'s Mot. at 11.) According to the Secretary, the proper denominator would be 249, which represents all of EMMC's dialysis

[4] There is another issue about the significance of patients' length of stay at an ESRD facility. The PRRB and CMS found it an obstacle to their review of the ASI exception request that EMMC had not fully documented the length of stay of its patients at the facility. (AR at 9, 235.) EMMC's ASI request is premised entirely on "increased caregiver time" (AR at 684) and the assumption that "an *unstable* diabetic patient *may* require one hour of additional licensed caregiver time . . . and a stable diabetic patient one-half hour" (AR at 685). Its cost computation then assumes that all 55 of its diabetic patients consume an entire additional hour of caregiver time three times per week and 52 weeks per year. (AR at 686.) I do not consider it arbitrary that CMS and the PRRB would expect length of stay data to confirm these assertions. Indeed, the regulations call for such data on "each session." 42 C.F.R. § 413.184(b)(xi). EMMC would have this Court find, as a matter or law or policy, that length of stay is not a significant factor when a provider has increased the number of nurses on duty to address the atypical needs of its patients, because an increased nursing presence redounds to the benefit of all ESRD patients who become well sooner and depart from the hospital sooner. (Pl.'s Mot. at 11.) Thus, as with the IEF issue, EMMC essentially asks this Court to make fact findings and policy determinations in its favor and to ignore the stated rationale the PRRB gave for affirming the denial of EMMC's request: inadequate documentation. I do not think that the nursing/length of stay factor is so obvious for this Court to regard as arbitrary the PRRB's demand for length of stay data.

patients, including temporary and transient patients.[5] (Def.'s Mot. at 12.) According to EMMC, the proper denominator for its facility is 134, which represents EMMC's projected number of "permanent" patients. (Pl.'s Mot. at 10.) In EMMC's view, only the permanent dialysis patients are relevant to the ASI exception because, in theory, a hospital might have a high number of transient or temporary patients with atypically intense needs and it would not make sense for CMS to pay an ASI exception for every dialysis treatment to a provider whose permanent population of dialysis patients (comprised of patients receiving multiple weekly treatments throughout the year) does not require atypically intense services. (Pl.'s Response at 3, Docket No. 17.) The rub here is that permanent patients receive far more treatments over the course of the year than transient or temporary patients, so a large population of atypically intense permanent patients could drive the provider's costs up even if that population is not a substantial proportion of the provider's overall patient base. It is presumably because of this concern that the regulations require, again, that a provider "demonstrate that a substantial proportion of its outpatient maintenance dialysis *treatments* involve atypically intense dialysis services." 42 C.F.R. § 413.184(a)(1) (emphasis added). Yet, despite this language, both parties to this dispute appear to be content to base the "substantial proportion" calculation on numbers of patients, rather than numbers of treatments. Using this approach, and using the total ESRD patient population (223) for the denominator and the diabetic patient population for the numerator (55), would result in a figure of approximately 25 percent, below the 33 percent that the parties say is

[5] I note that Exhibit 18 suggests there were 223 patients who received dialysis services in the year in question. (AR at 932.) I have not actually counted the number of patients listed (but not numbered) in Exhibit 17 (AR at 920-924), but EMMC represents that Exhibit 17 reflects 218 patients. On page 21 of its request, however, EMMC asserts that there were 248 "admissions." (AR 687.) The Secretary asserts yet another number, 249. (Def.'s Mot. at 12.) I do not know where that number comes from. In its rejection of the Intermediary's recommendation, CMS observed "some discrepancies" in Exhibit 17 that frustrated a determination of how many dialysis patients EMMC had, concluding that "EMMC has somewhere between 134 patients and 251 patients." (AR at 235). Obviously, using 134 rather than 251 as the total number of dialysis patients would yield widely disparate ratios of atypically intensive patients.

the average for the percentage of patients requiring atypically intense dialysis services in hospitals around the country.

In any event, I find it impossible to refute the Secretary's position on the inadequacy of EMMC's documentation because I see no reasonable basis to conclude that the Secretary's assertion that the total number of patients receiving outpatient dialysis treatments should serve as a denominator is any less accurate than EMMC's assertion that the denominator should be the total number of permanent patients receiving outpatient dialysis treatments. Furthermore, EMMC's request and documentation do not even address the "substantial proportion" issue in terms of the total number of outpatient dialysis treatments provided to diabetic patients as compared with the total number of outpatient dialysis treatments provided to all other patients.[6] Although CMS or the PRRB might have been able to extract that information from Exhibits 17 and 18 (assuming they cross referenced the names listed on each document), I fail to understand why EMMC did not perform this operation before filing its exception request. Ultimately, I cannot conclude that it was arbitrary or capricious for the PRRB to deny EMMC's ASI exception request based on inadequacies in the documentation when that documentation (a) does not afford

[6] At page 18 of EMMC's request (AR at 686), there is a text box in which EMMC asserts that 55 diabetic patients received 3 treatments per week for 52 weeks (N.B.: Exhibit 18 suggests that the number of treatments per patient per month is anything but uniform). That comes to 8,580 treatments. This number is curious because EMMC also represents on page 18 that there were only 11,108 treatments given. If one were to paint with similarly broad brushstrokes to estimate the number of treatments provided to the other patients, there would be some 12,324 treatments for the remaining permanent population of 79 patients (assuming 134 permanent patients in all) plus, say, 267 treatments for the 89 temporary/transient patients (using as figures 223 total patients less 134 permanent patients and arbitrarily assigning a week's worth of 3 treatments for each because Exhibit 18 does not supply information on the number of treatments given to most of the temporary/transient patients). This rough estimate of the total number of treatments provided to both diabetic patients and all other patients would come to 21,171. The ratio of 8,580 over 21,171 is 0.405. Does 40.5 percent reflect that a "substantial proportion" of EMMC dialysis treatments went to patients having atypically intense needs or is it roughly in line with the national average? I do not know and, of course, I do not believe the question is even germane given the posture of this case. I embarked on this digression only as a way of articulating why I harbor doubts about EMMC's broad generalizations and conclusory assertions as to how clear and convincing its documentation is with regard to how atypically intensive its ESRD patients are.

On a separate matter, I also observe that EMMC flat out misconstrues the record in its motion, asserting that CMS "found" that 59 percent of EMMC's patients required atypically intense services. (Pl.'s Mot. at 11-12.) A review of the third page of the CMS findings (AR at 234-238) reflects that CMS merely characterized EMMC as making that assertion. CMS clearly did *not* make the finding that EMMC says it did.

"convincing objective evidence" that a substantial proportion of EMMC's entire outpatient dialysis population required atypically intense services during the year in question[7]; (b) lacks length of stay data to corroborate the assertion that 55 diabetic patients consume an additional hour of nursing time per treatment, which consists of the lion's share of the costs underlying the exception request; and (c) is not even addressed to the question of whether a substantial proportion of the total number of outpatient dialysis treatments provided in the year in question went to patients requiring atypically intense services.

3. Accelerated training

Medicare regulations permit a provider to bill Medicare for time spent training patients how to perform self-dialysis, training that is typically afforded to patients having home dialysis equipment. 42 C.F.R. § 413.190(a). The regulations provide that the provider may only bill Medicare for training on dates that dialysis treatments are also provided. Id. § 413.190(f)(1). There is, predictably, an exception:

> If an ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the --
>
> (i) Facility's projected training cost per treatment; or
>
> (ii) Cost per treatment the facility would have received in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

Id. § 413.190(f)(2). Also predictably, there are hoops the provider must jump through. Among other things:

> (6) The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's --

[7] The so-called "atypical patient mix" issue is actually generated by subsection (a)(2) of the ASI regulation rather than (a)(1). Compare 42 C.F.R. § 413.184(a)(1) with (a)(2).

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

(7) The total treatments from the patient list must be the same as the total treatments reported on the cost report filed with the request.

Id. § 413.190(f)(6) & (7).

EMMC sought a modest exception for its provision of accelerated training (AT) to patients having home dialysis machines. CMS denied the request based on inadequate documentation. CMS's disparagement of the documentation can be found at page 237 of the record. The gist of its finding was that EMMC failed to "delineate the type of training sessions being utilized" or which patients were trained under what "modality." Based on these omissions, CMS concluded that it could not grant an exception because "EMMC has not provided a satisfactory patient schedule or cost by each of the two training modalities." (AR at 237.) The PRRB affirmed CMS's denial of this exception as well based, once again, on poor documentation. In its findings, the PRRB related:

> [B]ecause the Provider's submitted patient listing was deficient regarding the identification of modalities as well as the number of treatments, the amount exceeding the composite rate could not be determined.

(AR at 9.)

According to EMMC's request, it has a self-dialysis training program that is designed to train patients over a period of five consecutive eight-hour days rather than 15 two-to-three-hour sessions spread over the course of five weeks. (AR at 688, 690.) The portion of EMMC's request that addresses the accelerated training exception can be found at pages 688 through 691 of the record. On page 691 the request contains a chart that lists Patients "A" through "O,"

provides each patient's age and states that each patient "Completed training." That is as close as the request comes to providing a "list of patients, by modality, trained during the most recent cost report period." The patients are not named, nor are their training "modalities" indicated. Moreover, the request does not include data concerning how many training sessions any of the patients actually participated in. Instead, as the Secretary points in his motion, EMMC simply asserts in its narrative that patients "usually" attend five training sessions. (Def.'s Mot. at 15-16, citing AR at 288.) Finally, as observed by both CMS and the PRRB, there is no computation that reveals the amount by which EMMC's actual training costs per treatment exceed the composite rate they received. Thus, there is no way to determine whether EMMC's request for, essentially, ten additional composite rate payments per trainee is "*the lesser of*" its "projected training cost per treatment" or the "[c]ost per treatment the facility would have received . . . if it had trained patients only during a dialysis treatment, that is, three times per week." 42 C.F.R. § 413.190(f)(2) (emphasis added). I agree with the Secretary that it was not arbitrary to deny the AT exception request.

4. Other

EMMC argues that all of the individual cost elements asserted in its request that were not specifically denied should be deemed approved. (Pl.'s Mot. at 13.) The problem with this argument is that each of the various cost categories EMMC speaks of (hardware/software costs, third shirt utilization, on-call hours, overtime due to travel and overall increased costs) are all components of EMMC's IEF request, which was denied on grounds that were not arbitrary and capricious. I reject this plea because EMMC has not articulated what legal basis might exist for this Court to affirm the denial of the IEF request yet still order the request to be granted in certain particulars. Indeed, the regulations clearly indicate that an exception to the composite

rate must be premised upon the provider's ability to demonstrate that the costs at issue are attributable to the criterion at issue, such as the IEF criterion. 42 C.F.R. § 413.182.

EMMC also maintains that the Court ought to consider whether EMMC "substantially complied" with the governing regulations, arguing that CMS and the PRRB imposed a "strict compliance" standard to deny EMMC's request. (Pl.'s Mot. at 18-19.) Assuming that Medicare administrators might well hold providers to a substantial compliance standard in their review of composite rate exception requests, I fail to see how this Court is in a better position than these administrators to determine when non-compliance with a regulation requiring documentation presents a material obstacle to the determination of a composite rate exception request. In any event, the law is clear that the arbitrary and capricious standard governs this Court's review of the administrative action.

B. Due Process

EMMC argues that the case should be remanded for a new hearing before the PRRB based on the PRRB's failure to grant a request that the individuals who performed subordinate administrative review be subpoenaed to testify as to their decision-making process and to produce their files related to EMMC's request. (Pl.'s Mot. at 20-21.) The record reflects that EMMC sought subpoenas to obtain testimony from Michelle Eliasen, the Intermediary staff member who first reviewed EMMC's request, and from Mark Horney, the CMS staff member who rejected the Intermediary's recommendation. In addition, EMMC sought subpoenas to obtain all documents "reviewed, consulted or prepared" by both Eliasen and Horney during the review process. (AR at 181, 183.) Finally, EMMC sought information through Mr. Horney of "all documents detailing the number of ESRD composite rate payments exceptions requests filed" by other providers within the same exception request window, "the basis for each such

request," "the number of such requests that were recommended for approval by a fiscal intermediary, and the number of such requests that were affirmatively approved by CMS." (AR 183-84.) The PRRB denied these requests. With regard to Ms. Eliasen, the PRRB indicated that because she had offered only a non-binding recommendation her testimony would not "be relevant to the determination of whether the Provider has furnished evidence that it meets the criteria for one or more of the ESRD exceptions." (AR at 164-65.) With regard to Mr. Horney, the PRRB indicated that documents he prepared or reviewed were covered by "the deliberative process privilege" and that documents pertaining to the exception requests filed by other facilities had no relevance to EMMC's request. (AR at 165.)

In Aroostook Medical Center v. Leavitt, this court considered a similar appeal. See 365 F. Supp. 2d at 55-56. The court concluded that it was an abuse of discretion for the PRRB to deny a subpoena request for the Intermediary staff member who reviewed Aroostook Medical Center's (AMC's) exception request "[b]ecause the Intermediary made calculations and conclusions based on the materials submitted to it by AMC, and because 42 U.S.C. § 1395oo(d) requires all evidence considered by the Intermediary to be presented to the Board." Id. at 56-57. The court concluded that the Intermediary staff member's "testimony, and the documents considered by [him were] highly relevant in resolving the disputes related to the cost report and other issues pertaining to the merits of AMC's request." Id. at 57. However, the court also concluded that it was not an abuse of discretion to deny the subpoena request for the CMS staff member because he was not the only individual who could testify as a representative of CMS and another CMS staffer did appear and testify at the hearing.

The Secretary's opposition to this aspect of EMMC's motion is not very forceful, perhaps due to the ruling in Aroostook Medical Center. The Secretary's motion, which was filed after

EMMC's motion, includes a section in which the Secretary indicates that, if the case were remanded, he "would not object to a remand order that provides much of the information and testimony sought by plaintiff." (Def.'s Mot. at 18.) Nevertheless, the Secretary has also indicated that Ms. Eliasen is no longer employed by the Intermediary and, thus, according to the Secretary, the PRRB cannot compel her to attend a hearing. (Id.) The Secretary also objects to any order to issue a subpoena for the production of "all notes and drafts" or "internal communications" reviewed or prepared by the Intermediary or by CMS, again raising the deliberative process privilege. (Id. at 18-19.) Finally, the Secretary contends that EMMC's request for a subpoena for certain documents related to exceptions requests filed by other providers should not be granted because any such documents are irrelevant to EMMC's request. (Id. at 19.)

Subsection (d) of 42 U.S.C. § 1395oo, relied upon in Aroostook Medical Center, provides that "[a] decision by the Board shall be based upon the record . . ., which shall include the evidence considered by the intermediary." CMS publishes a Provider Reimbursement Manual (PRM) that is available on its website.[8] The parties frequently refer to the PRM in their motions. EMMC refers to the PRM as evidence of the role the Intermediary plays in the development of the record that should be considered by the PRRB on appeal from a CMS denial. In particular, § 2723 and its subsections relate to the responsibilities of intermediaries. The initial paragraph of § 2723 relates the following:

> When the renal facility fails to submit the required documentation (see §2721), the exception request is returned to the facility. (See §2723.3A.) The 60 working days [for comprehensive administrative review] starts when the renal facility files an exception request with all required documentation with the intermediary during the intermediary's regular business hours, subject to the 180 day time period for requesting an exception. (See §2723.3A.)

[8] http://www.cms.hhs.gov/manuals/pub151/PUB_15_1.asp

This language demonstrates the significance of the background fact that EMMC filed its exception request just four days prior to the close of the 180-day window for filing the request. EMMC makes much of the fact that the Intermediary did not return its exception request for failure to submit all the proper documentation, as though this were proof positive that the documentation it submitted was in compliance with the regulations. Of course, if the Intermediary had done so, EMMC likely would have been in *no* position to rectify the problem given the fact that the request was filed on the Thursday preceding the Monday deadline and Ms. Eliasen had 15 days to conduct her review. See PRM § 2720.2 ("Failure by a facility to submit its exception request within 180 days results in the exception request being denied. In addition, neither HCFA nor intermediaries may extend the 180-day time frame for filing an exception. Therefore, if the intermediary returns a facility's exception request for any reason, the facility must resubmit its request to the intermediary within the 180-day time frame."). Moreover, the fact that the Intermediary did not reject the request is a fact for CMS and the PRRB to weigh like any other; even if the Intermediary were to testify that EMMC's documentation was complete, that would not preclude CMS or the PRRB from drawing a contrary conclusion based on an independent review of EMMC's exception request and documentation.

EMMC's position appears to be that an intermediary must be required to divulge its entire file to a provider before a PRRB hearing and to present a suitable staff member to testify before the PRRB so that the provider and the PRRB might determine whether the intermediary somehow supplemented the provider's documentation. Thus, at page seven of its motion, EMMC suggests that the Intermediary already had in its possession "Worksheet S-5" and was already "familiar" with EMMC's historic cost reports.[9] The problem with these critiques is that

[9] EMMC also focuses on the PRRB's concern that EMMC did not submit a "cost report comparison." (Pl.'s Mot. at 7.) EMMC is correct that it was not required to submit this comparison of its annual cost reports in its

they totally disregard the fact that the regulations require EMMC to submit copies of these documents with its exception request and EMMC did not do so.

EMMC also contends that the record might have been supplemented by the Intermediary with regard to the question of whether any of the nearby dialysis facilities had the capacity to absorb EMMC's ESRD patients or had a willingness to expand in order to do so. (Pl.'s Mot. at 8-9.) According to EMMC, the responsibility for making that determination falls on the Intermediary. (Id. at 9, citing PRM § 2725.3.F.) The PRM provides:

> F. Intermediary Documentation.-- In addition to the requirements in § 2723:
>
> 1. The intermediary obtains copies of the yellow page advertisements for each city in which a nearby dialysis facility (as detailed by the provider) is located. Specifically, it looks under hospitals, clinics, medical facilities, etc. The intermediary copies the pages and submits them along with the name of the phone directory to HCFA.
>
> 2. The intermediary contacts each of the nearby facilities or hospitals to determine the number of openings for patients that they currently have. Assuming that the nearby facilities do not have the current capability to handle the increased number of ESRD patients, the nearby facilities are asked if they are able to or willing to expand through additional space or additional shifts to handle the number of patients that may be displaced by the filing ESRD facility in the event that this facility closes. The results of these contacts are included in the intermediary's report to HCFA.

PRM § 2725.3.F. In addition, § 2725.3.A states that, with respect to an IEF exception request, "[t]he . . . intermediary is responsible for reviewing and corroborating the information submitted." I do not agree with EMMC that the placement of the duties of review and corroboration on the intermediary absolves the provider from independently supporting its IEF exception request with affirmative evidence that nearby ESRD facilities are not prepared or would not be willing to take steps necessary to absorb the provider's ESRD patients. See PRM § 2725.3.E ("When a facility claims that the nearest ESRD facilities are at capacity and cannot

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request. See PRM § 2725.3.D. However, the record reflects that EMMC did not even submit a copy of its most recent cost report, which is a basic regulatory requirement.

expand, some documentation, such as a written statement from the nearest ESRD facilities, must be included to substantiate the exception request. An unsubstantiated general statement does not form the basis to justify an exception."). In other words, it appears clear to me from the regulations that an exception request would be appropriately denied if a provider failed to properly document its request and the intermediary, for whatever reason, failed to fill in the void. The intermediary's quality control review and corroboration functions do not absolve the provider of carrying its burden in the first instance.

At heart, EMMC's contention that the denial of its subpoena requests prevented EMMC from receiving "due process" is built on an assumption that it is *entitled to supplement* its deficient documentation during a PRRB hearing by questioning the intermediary's and CMS's staff members and by incorporating whatever papers may have been "reviewed, consulted or prepared" by the intermediary or by CMS in review of EMMC's exception request. Section 1395oo does make the work product of the intermediary relevant to the PRRB's ultimate determination because it requires that the PRRB's decision "be based upon the record . . ., which shall include the evidence considered by the intermediary." However, there is no basis in the regulation to support EMMC's contention that it should be able to question the intermediary's staff concerning the thought processes that went into a recommendation. Nor is there any basis in the regulations or in any precedent that I can find for EMMC's subpoena request to obtain CMS staff member Horney's work product or testimony from him regarding his deliberative process. I therefore find that it was not an abuse of discretion to deny the subpoena requests targeting CMS and Horney or even Eliasen, to the extent EMMC desired to question Eliasen about her deliberative process rather than simply what evidence she considered in making her recommendation. The question remaining is whether EMMC has established that the denial of

the subpoena request for Eliasen's documents or testimony from Eliasen relating to what evidence she "reviewed, consulted or prepared" was an arbitrary or capricious exercise of the PRRB's authority. I address this question because, in my view, although § 1395oo requires that the PRRB consider all of the evidence considered by the intermediary, that does not impose a procedural requirement that the intermediary testify, let alone under the compulsion of a subpoena or, necessarily, that the documents or other sources consulted by the intermediary must be disclosed to the provider. There would appear to be reasonable alternative means to ensure that all of the evidence considered by the intermediary is preserved for the PRRB. In fact, the PRM already requires the intermediary to forward to CMS the intermediary's worksheets and the results of the intermediary's IEF inquiries or "contacts." See PRM §§ 2723.3.F & 2725.3.F.

Ultimately, I am troubled by the inefficiencies that might arise from an order of remand. In effect, the Court would be remanding the case without any basis to conclude that there was, in fact, material evidence supplied by the Intermediary that was never incorporated in the record. Eliasen's own report describes her role as one of "cursory review." (AR at 1310.) A court might consider whether evidence outside the administrative record can demonstrate "prejudicial procedural irregularity." Digregorio v. Hartford Comprehensive Employee Benefit Serv. Co., 423 F.3d 6, *16 (1st Cir. Sept. 8, 2005) (quoting Orndorf v. Paul Revere Life Ins. Co., 404 F.3d 510, 520 (1st Cir. 2005)). In Digregorio, the beneficiary of an ERISA plan asked the court to find arbitrary and capricious an adverse benefits determination issued by the plan administrator because the administrator had rejected her request for a copy of her complete claim file, which, allegedly, deprived her of a full and fair review. Id. Although the Court of Appeals concluded that the beneficiary was entitled by law to the copy of her file, it concluded that the District Court appropriately denied a remand because the beneficiary failed to demonstrate that her claim

would have been resolved any differently had the copy been provided. Id. at *16-17. I find that logic to apply with equal force to this case. EMMC has not shown that the PRRB's denial of the subpoena requests prejudiced its ability to obtain a fair hearing before the PRRB.[10] In the absence of any evidence that the Intermediary withheld relevant materials from the PRRB or that the PRRB failed to consider certain materials forwarded to CMS by the Intermediary, I recommend that the Court reject EMMC's "due process" argument.

CONCLUSION

For the foregoing reasons, I **RECOMMEND** that the Court **DENY** the plaintiff's motion for judgment and **GRANT** the defendant's motion for judgment.

NOTICE

> A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which *de novo* review by the district court is sought, together with a supporting memorandum, and request for oral argument before the district judge, if any is sought, within ten (10) days of being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within ten (10) days after the filing of the objection.
>
> Failure to file a timely objection shall constitute a waiver of the right to *de novo* review by the district court and to appeal the district court's order.

/s/ Margaret J. Kravchuk
U.S. Magistrate Judge

Dated October 27, 2005

EASTERN MAINE MEDICAL CENTER v. HEALTH AND HUMAN SERVICES, SECRETARY
Assigned to: JUDGE D. BROCK HORNBY
Cause: 42:1395 HHS: Adverse Reimbursement Review

Date Filed: 01/14/2005
Jury Demand: None
Nature of Suit: 151 Contract: Recovery Medicare

[10] Of course, EMMC would be hard pressed to make a prejudice showing in light of the fact that EMMC had the obligation to fully document its exception request.

Jurisdiction: U.S. Government Defendant

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